



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that STRENSIQ (asfotase alfa), manufactured by Alexion Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6408, Silver Spring, MD 20993-0002, 301-796-4842, FAX: 301-796-9858, email: larry.bauer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that STRENSIQ (asfotase alfa), manufactured by Alexion Pharmaceuticals,

Inc., meets the criteria for a priority review voucher. Asfotase alfa is a long-term enzyme replacement therapy for patients with infantile- and juvenile-onset hypophosphatasia (HPP). HPP is a rare genetic disorder that affects the development of bones and teeth.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>.

For further information about STRENSIQ (asfotase alfa), go to the Drugs@FDA Web site at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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